UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/736,619	12/13/2000	Igor Markidan	4389-9	8901

22442 7590 10/08/2004

SHERIDAN ROSS PC
1560 BROADWAY
SUITE 1200
DENVER, CO 80202

EXAMINER	
LANEAU, RONALD	

ART UNIT	PAPER NUMBER
3627	

DATE MAILED: 10/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/736,619	MARKIDAN ET AL.	
	Examiner	Art Unit	
	Ronald Laneau	3627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

1. The amendment filed on 06/01/04 has been entered. New claims 10-14 are added and claims 1-14 are now pending.

Claim Rejections - 35 USC § 101

2. The 101 rejections to claims 1-3 and 5 has been withdrawn in view of amendment to said claims to make it a computer-implemented database.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 3, 5, 6, 8, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jeatran, et al (5,898,586) in view of Milosavljevic et al (US 2004/0098204).

As per claim 1, Jeatran teaches a method for tracking samples of a clinical study (Abstract), comprising;

Defining a first clinical study protocol comprising a plurality of procedures, wherein said procedures comprise steps;

Accessioning samples for said first clinical study protocol by recording in a database identifying information for said samples and identification of said first clinical study (col. 2, lines l 1-32 - the sample, i.e. the drug is accessioned b/c the system is told what is being dispensed and

the study is identified b/c it is the only study for which the data is being recorded, it is the first because it is the only one being recorded and there is no other one claimed;

Creating a worklist by assigning a particular scientist to perform a particular procedure on particular samples (Abstract; Figs. 4 and 13; col. 2, lines 1 1-32 – particular scientists/investigators are assigned to perform, i.e. administer the samples, a particular procedure on particular samples, the "worklist" is in essence created when the computer system provides the medications, and creates and identity check by study id and Pm and performing a match before retuning the checklist;

Creating a checklist comprising the steps of at least one procedure to be performed on the samples of a worklist (Abstract; Figs. 3-33 - the checklist is a verbal list via the telephone that is input by the scientist/investigators based on the sample and the patient);

Performing the steps on the checklist (Abstract; Figs. 3-33 - the steps are walked through to ensure that compliance with the protocol is met;

Recording in said database completion and results of at least a portion of said steps on said checklist (Abstract; Figs. 3-33, i.e. commit randomization file and patient file changes to the database step 131, commit changes to database step 179, save bottle status step 178). Jeatran teaches as set forth above. However, Jeatran does not specifically teach that clinical protocols encompass multiple procedures, although Jeatran does teach the specific procedure steps set forth. The examiner takes Official Notice that clinical protocols must be developed and approved and that they encompass multiple procedures. Evidence to support this statement includes the fact that there are multiple regulations governing the design of clinical protocols in various countries, new drug design is more complex and proving the efficacy and safety can be critical to

the manufacturer and it can take over eight years for a new drug to get FDA approval and includes multiple clinical studies, under a clinical protocol, which are the premarket testing ground for unapproved drugs to evaluate safety and effectiveness in treating, prevent, or diagnosing a specific disease or condition. See, e.g. CDER Handbook, pp. 3-29.

Jeatran does not teach displaying a checklist, initiating a query of said database and generating a report in response to said query but Milosavljevic et al teach displaying a checklist to said first scientist wherein said first scientist performs said steps of said first checklist (page 11, [0133], lines 4-13); create a checklist for each procedure on a set of samples in the database (page 12, [0145], lines 1-5); initiating a query of said database for a status associated with at least a first of accessioned samples and generating a report in response to said query, said report including at least some of said completion status or results stored in said database, wherein a status of said at least a first of said accessioned samples is tracked (page 12, [0142], lines 7-12, [0143], lines 1-3).

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the checklist display as taught by Milosavljevic et al into the system of Jeatran because it would decrease greatly any error in performing a procedure on the samples since the checklist will be displayed in front of the scientist performing said procedure. And it would have been obvious to one of ordinary skilled in the art at the time the invention was made to have included an approved clinical study, i.e. defined clinical study, which encompass multiple procedures, to modify Jeatran because a clinical study involving human beings and pharmaceuticals cannot be conducted without such a protocol. Alternatively, pharmaceutical companies would want to ensure that they have complete documentation that they have done everything in their power to

ascertain the safety of a drug/pharmaceutical before releasing it for general consumption due to the huge liability risks involved, for example Eli Lilly and defense of the Prozac litigation.

As per claim 3, Jeatran teaches the step of indicating completion and results of at least a portion of said steps on said checklist comprises indicating completion of at least one step for all samples on a checklist by one entry of information (Figs. 3-33, commit randomization file and patient file changes to the database step 131).

As per claim 5, Jeatran teaches the step of formalization of the results by an activity selected from the group consisting of entry of new results (Figs. 3-33, commit randomization file and patient file changes to the database step 131).

As per claim 6, Jeatran teaches a computer-implemented method for tracking samples of a clinical study (Abstract), comprising the steps of: Providing a computer having an associated memory (Fig. 3 - 61);

Providing a list of standard operating procedures, wherein each of said standard operating procedures comprise procedure steps (The Clinical Study Protocol/enrollment verification criteria verification, collection of patient response information, and changing of the individual patient treatment during the study based on the specific criteria - each study includes a set of specific minimum standards or enrollment criteria that each participant or patient must meet to be included in the study which is utilized to comprise the procedure steps, see col. 6);

Providing a list of samples (Fig. 1); and

Merging said list of standard operating procedures with said list of samples to generate a check list for use in connection with said clinical study, wherein said list of standard operating

procedure, said list of samples and said checklist are all stored in said computer memory (Figs. 2-33).

As per claim 8, Jeatran teaches a computer implemented method for tracking samples of a clinical study (Abstract), comprising:

Accessioning a plurality of samples, wherein identifying information is stored in said computer (Figs. 2-33, col. 2, lines 1 1-32 - the sample, i.e. the drug is accessioned b/c the system is told what is being dispensed and identified by the identification number);

Determining procedures to be taken with respect to said samples, wherein said procedures comprise a plurality of steps (Figs. 6-7 - get appropriate medication, confirm assignment, collect more study specific data associated with the medication being given, i.e. the samples);

Defining at least a first workgroup comprising at least a first of said plurality of samples (Abstract - assigning at least one investigator to administer the contents of the plurality of bottles, i.e. the investigator is the at least one workgroup and the plurality of bottles is the plurality of samples), wherein said first workgroup comprises at least one procedure (Abstract - administering the contents is the at least one procedure), and wherein said one workgroup is stored in said computer (providing sponsor computer means including telephone capabilities and for storing information, disseminating information, and instructions over the telephone to the investigators, and for receiving information from the investigators, the computer means operable, upon being contacted by the investigator and requiring caller identification Fig. 4 - 65, 66 and 67 in order to authenticate, i.e. the computer stores the workgroup);

Preparing at least one checklist comprising said at least a first workgroup and said steps comprising said at least one procedure, wherein said checklist is stored in said computer (Figs. 2-33 and Abstract);

Performing said steps (Figs. 2-33 and Abstract);

Recording performance of said steps in said computer (Figs. 2-33 and Abstract).

5. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jeatran (5,898,586) in view of Milosavljevic et al (US 2004/0098204) as applied to claim 1 above, and further in view of Oku, et al. (5,675,745) and in view of Tony Kennedy, Pharmaceutical Project Management, Vol. 86, 1998, pp. 109-1 12.

Jeatran teaches as set forth above. Jeatran does teach that the study id and the investigator id must match before access to the checklist can proceed (Fig. 13). However, Jeatran does not teach conducting the method steps with a second clinical study protocol. Kennedy teaches that because of the small size of some departments and the lack of sufficient numbers of qualified individuals within departments, many managers wind up assigning one person to more than one project team, i.e. a second clinical study protocol (pg. 1 11). Oku teaches that multiple clinical trials can be contained within the same system (Fig. 46), that the Workgroup list for a specific clinical trial can be accessed (Figs 48 and 4%, and that work management can be entered as assigned to a specific person for a specific task (Fig. 54). Oku further teaches that the database employs GCP, and that the work side model is made by employing the network used in the project management and stratifying roughly in the sequence of phase, clinical trial, working group, and work, i.e. by relating various documents with work flow, it is possible to retrieve

from other standpoints than structure of the document itself, such as job flow (col. 20, lines 21-60). Oku further teaches that you can drill down through the clinical trial to get to work progress list for each clinical trial (cols. 21-22, lines 50-52). Thus, Oku teaches that through the documents and project management tasks are allocated with instructions according to the protocol/sop and recorded in multiple clinical trials (Figs. 46, 48, 49, 54 and 58-62; cols. 20-22). Moreover, Oku teaches that research and development, was not being adequately addressed, as there existed a need to enhance productivity of routine tasks and non-routine tasks that can be addressed by standardized procedures (col. 1, lines 31-54).

It would have been obvious to have incorporated a second clinical trial into Jeatran as Kennedy teaches the need for reuse of personnel and Oku teaches that the implementation of multiple clinical trials for enhanced efficiency.

6. Claims 7, 9-11, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jeatran (5,898,586) in view of Milosavljevic et al (US 2004/0098204) as applied to claims 6 and 8 above, and further in view of William E. Evans and Mary V. Relling, Pharmacogenomics; Translating Functional Genomics into Rational Therapeutics, Science, Vol. 286, Issue 5439, October 15, 1999, pp. 487-491.

Jeatran teaches as set forth above. However, Jeatran does not teach that one of the procedures determines the genotype of an individual, although Jeatran does teach that study specific data may be collected (Fig. 7 - 1 18). Evans teaches determining the genotype of an individual in conjunction with clinical studies. Evans further teaches that determining an individuals genotype is associated with disease risk and drug toxicity, is likely to constitute part

of the mechanism for so-called "idiosyncratic drug reactions, drug-metabolism genotypes may result in a phenotype in the absence of drug, and that common polymorphisms in drug targets dictate that DNA sequence variations be taken into account in the genomic screening processes aimed at new drug development to provide new insights for the development of medications that target critical pathways in disease pathogenesis and medications that can be used to prevent diseases in individuals who are genetically predisposed to them. (Pp. 1-4 of 8 and Fig. 3) Evans thus teaches that automated systems are being developed to determine an individual's genotype for polymorphic genes that are known to be involved in the pathogenesis of their, disease, in the metabolism and disposition of medications, and in the targets of drug therapy, which need be performed only once for each battery of genes tested and can then become the blueprint for individualizing drug therapy. (Pg. 6 of 8 and Fig. 3) Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have included determining an individuals genotype as taught by Evans into the system and method of Jeatran for the specific reasons set forth in Evans.

7. Claims 4 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jeatran (5.898,586) in view of Milosavljevic et al (US 2004/0098204) as applied to claim 1 above, and further in view of Willimn E. Evans and Mary V. Relling, Pharmacogenomics: Translating Functional Genomics into Rational Therapeutics, science, Vol. 286, Issue 5439, October 15, 1999, pp. 487-491.

Jeatran teaches as set forth above. However, Jeatran does not teach that one of the procedures determines the genotype of an individual, although Jeatran does teach that study

specific data may be collected (Fig. 7 - 1 18). Evans teaches determining the genotype of an individual in conjunction with clinical studies. Evans further teaches that determining an individuals genotype is associated with disease risk and drug toxicity, is likely to constitute part of the mechanism for so-called fidiosyncratic drug reactions, drug -metabolism genotypes may result in a phenotype in the absence of drug, and that common polymomhisms in drug targets dictate that DNA sequence variations be taken into account in the genomic screening processes aimed at new drug development to provide new insights for the development of medications that target critical pathways in disease pathogenesis and medications that can be used to prevent diseases in individuals who are genetically predisposed to them. (Pp. 1-4 of 8 and Fig. 3) Evans thus teaches that automated systems are being developed to determine an individual's genotype for polymorphic genes that are known to be involved in the pathogenesis of their, disease, in the metabolism and disposition of medications, and in the targets of drug therapy, which need be performed only once for each battery of genes tested and can then become the blueprint for individualizing drug therapy. (Pg. 6 of 8 and Fig. 3) Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have included determining an individuals genotype as taught by Evans into the system and method of Jeatran for the specific reasons set forth in Evans.

Response to Arguments

8. Applicant's arguments filed on 6/01/04 have been fully considered but they are not persuasive.

Applicant argues that Jeatran does not describe a method that includes providing list comprising laboratory procedures to be performed on samples of biological material, checklists of procedures to be performed with respect to those samples. Contrary to applicant's arguments, these limitations are met by the newly added reference. Furthermore, applicant argues tat Evans does not teach, suggest or disclose a method that includes generating a checklist of procedures to be performed on samples, the newly added reference in Milosavljevic et al teaches said limitation (see above). Applicant's argument having been found to be unpersuasive, the rejection has not been withdrawn.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ronald Laneau whose telephone number is (703) 305-3973. The examiner can normally be reached on Mon-Fri from 8:30am - 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Olszewski can be reached on (703) 308-5183. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RL
Ronald Laneau
Examiner
Art Unit 3627

9/30/01
Primary Examiner

rl